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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,136

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Rebecca Louise Charles nee Newsham

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UNILEVER PATENT GROUP
800 SYLVAN AVENUE
AG West S. Wing
ENGLEWOOD CLIFFS, NJ 07632-3100

EXAMINER

FLOOD, MICHELE C

ART UNIT

PAPER NUMBER

1655

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,136	Applicant(s) CHARLES NEE NEWSHAM ET AL.	
	Examiner Michele Flood	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10, 16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/18/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on September 16, 2008 with the cancellation of Claims 1-7 and 11-15, and the addition of newly submitted Claims 16 and 17.

Election/Restrictions

Applicant's election with traverse of the species of Claim 8; and, the species of Claim 16 in the reply filed on January 6, 2009 is acknowledged. The traversal is on the ground(s) that dependent Claims 9 and 10 belong to the same invention as Claim 8 because the claims include the same chemical components but narrow the scope of the invention through the application of selection criteria that are disclosed in and are within the scope of the parent claim. This is not found persuasive because while the ingredients for administration are essentially same, the route of administration for each of the claim-designated ingredients are different, each one from the other as set forth in the limitations in Claims 9 and 10; and, therefore the methods are dependent each one from the other and patentably distinct.

The requirement is still deemed proper and is therefore made FINAL.

The species election of Claim 16 was not found; therefore, Claim 17 was taken into consideration.

Claims 8, 16 and 17 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "the ratio of light melanin to dark melanin" in line 1. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by replacing "the" with a.

Claim 8 recites the limitation "the other components" in line 4. There is insufficient antecedent basis for this limitation in the claim.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perrier et al. (A*) in view of Naito et al. (N) and Bissett et al. (WO 98/34591 A1).

Applicant claims a method of increasing the ratio of light melanin to dark melanin in the skin of a mammal, the method comprising administering to said mammal effective amount of (a) a flavanoid, (b) vitamin C and (c) vitamin E wherein at least component (b) is administered systemically and the other components are administered topically. Applicant further claims the method according to claim 8 wherein the flavanoid comprises one or more flavones.

Perrier teaches a method of topically applying to the skin of a mammal an effective amount of a composition comprising an extract of *Saxifrage* which comprises proanthocyanidins such as woogonin (a flavonone), baicalin (a flavanoid) and baicalein (a flavone), a mulberry (*Morus nigra*) extract, a *Scutellaria* (*Scutellaria baicalensis*) extract and a grape (*Vitis vinifera*) extract. The method taught by Perrier inhibits the formation of unwanted pigmentation by inhibiting tyrosinase. Therefore, the method taught by Perrier is deemed to inherently provide a method of increasing the ratio of light melanin to dark melanin in the skin of a mammal.

The teachings of Perrier are set forth above. Perrier teaches the instantly claimed method except for (b) vitamin C and (c) vitamin E, wherein vitamin C is administered systemically and wherein vitamin E is administered topically. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredients and process steps for the administration of the claim-designated ingredients to the method taught by Perrier to provide the claimed method because at the time the invention was made Naito taught a composition comprising vitamin C for oral administration for skin whitening and removing stain from skin; and, Bissett taught a topical composition comprising tocopherol sorbate (vitamin E) for use in a method of lightening skin. At the time the invention was made, one of ordinary skill in the art would have been motivated and would have had a reasonable expectation to add the composition taught by Naito for oral administration and the composition taught by Bissett for topical administration to the method taught by Perrier to provide the instantly claimed method of increasing the ratio of light melanin to dark melanin in the skin of a

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mammal because Naito taught that compositions comprising vitamin C could be administered as a drink to a mammal to lighten the skin of a mammal; and, Bissett taught that compositions comprising vitamin E could be topically administered to the skin of a mammal to provide a method of lightening hyperpigmented regions in skin.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claimed ingredients in the making of the claimed method of treatment because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Thus, at the time the invention was one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the oral vitamin C used in the method of skin lightening taught by Naito and the topical vitamin E used in the method of reducing skin hyperpigmentation taught by Bissett to the topical composition comprising proanthocyanidins used in the method of inhibiting the formation of unwanted skin pigmentation taught by Perrier because the claimed invention is no more than the combining of well known ingredients used in well known methods for increasing the ratio of light melanin to dark melanin in the skin of a mammal when administered by specific routes of administration.

Therefore, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Allowable Subject Matter

Claim 16 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
April 13, 2009

/Michele Flood/
Primary Examiner, Art Unit 1655